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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,314	12/16/2003	Yogesh B. Gianchandani	30275/2419	5950

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MARSHALL, GERSTEIN & BORUN LLP  
233 SOUTH WACKER DRIVE  
6300 SEARS TOWER  
CHICAGO, IL 60606-6357

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/737,314

**Applicant(s)**

GIANCHANDANI ET AL.

**Examiner**

DIANE YABUT

**Art Unit**

3734

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 36-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 36-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/12/2009 has been entered.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6, 8-16, 36-39, 41-44 are rejected under 35 U.S.C. 102(a) as being anticipated by **Leopold et al.** (U.S. Pub. No. **2002/0173839**).

Claims 1-3, 6, 8-16, 36-39, 41-44: Leopold et al. disclose a planar structure expandable into a 3-D structure or tubular stent, the planar structure comprising first and second spaced side beams or hinges **126** which extend continuously along a

longitudinal axis, and a plurality of spaced cross-bands or folded/looped beams which connect the side beams together wherein a first set of the cross-bands **122** are expandable in a first direction substantially perpendicular to the longitudinal axis to form a 3-D structure and wherein a second set of the cross-bands **124** are expandable in a second direction substantially opposite the first direction to form a mesh-like 3-D structure (Figures 19-21; paragraphs 72-76). The folded beams have an involute or curved pattern and switchback or alternating pattern. The stent may be coated with a biocompatible surface coating and is made of a biocompatible material or shape-memory alloy (paragraph 65).

4. Claims 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by **Fischell et al.** (U.S. Patent No. **6,086,604**).

Claims 46-47: Fischell et al. disclose a unitary stent structure disposed in a plane when in a non-expanded or non-deployed position and having a longitudinal axis, first **4T** and second **4B** parallel spaced apart side beams which extend parallel along the longitudinal axis, and a plurality of spaced cross-bands including a series of folded beams having an involute or switchback pattern which connect the side beams together wherein a first set of the cross-bands **2'''** are expandable in a first direction substantially perpendicular to the longitudinal axis to form a 3-D structure (Figures 6-9). A second set of the cross-bands **2'''** are expandable in a second direction substantially opposite the first-direction to form a mesh-like tubular 3-D structure and each of the cross-bands include hinges (**4R** and **4L**) for interconnecting adjacent folding beams and allowing

folded back beam sections to rotate relative to one another about a rotation axis (from Figure 4 to Figures 6-7).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**).

Claims 4-5: Leopold et al. do not expressly disclose the stent plastically deforming during expansion in order to be free-standing. However, this would depend on the material of the stent, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plastically deformable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Plastically deformable materials are also well known in the art for deploying stents.

7. Claims 7, 17, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Smith et al.** (U.S. Pub. No. **2002/0156525**).

Claims 7, 17, and 40: Leopold et al. disclose the claimed device except for the planar structure including a conductive foil and the sheet material including conductive foil, and

wherein side beams and cross-bands are formed by electric discharge machining the conductive foil, and wherein a longest beam section of the plurality of interconnected and folded back first and second beam sections extends parallel to the longitudinal axis.

Smith et al. teach a conductive foil and the sheet material including conductive foil, and wherein side beams and cross-bands are effectively formed by electric discharge machining the conductive foil (paragraph 33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide conductive foil and forming the cross-bands by electric discharge machining, as taught by Smith et al., to Leopold et al. in order to form the stent "faster and with higher quality." Smith et al. also teach a longest beam section **100** of the plurality of interconnected and folded back first and second beam sections extends parallel to the longitudinal axis (Figures 1-2b). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the cross-bands of Leopold et al. to a plurality of interconnected and folded back first and second beam sections extends parallel to the longitudinal axis, as taught by Smith et al., in order to enhance the kink resistance and flexibility of the cross-bands (paragraph 29).

8. Claims 18-23, 25, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Pacetti** (U.S. Pub. No. **2002/0188345**).

Claims 18-23, 25, and 45: Leopold et al. disclose the claimed invention, including the 3-D structure comprising a helical coil including first and second spaced rings at

opposite ends thereof and wherein each of the rings is formed by an adjacent pair of expanded crossbands (hinges 126 may be on both sides of the stent to form rings and a helical coil, paragraph 73), except for at least the first side beam including a link portion being thinned or being made of a fragile material relative to the other portions of the first side beam having a mechanical strength lower than other portions of the first side beam to allow the first side beam to break at the link portion during expansion of the first set of cross-bands, the structure comprising at least one electrical inductor.

Pacetti teaches at least a first side beam including a link portion being thinned or being made of a fragile material relative to the other portions of the first side beam having a mechanical strength lower than other portions of the first side beam to allow the first side beam to break at the link portion during expansion of the first set of cross-bands, the structure comprising at least one electrical inductor (paragraphs 23 and 36). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a weak link portion, as taught by Pacetti, to Leopold et al. in order to facilitate imaging the stent with MRI.

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Pacetti** (U.S. Pub. No. **20020188345**), as applied to claim 23 above, and further in view of **Da Silva et al.** (U.S. Patent No. **6,729,336**).

Claim 24: Leopold et al. disclose the claimed device including a first ring and side beams and cross-bands, except for the elements including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure.

Da Silva et al. teach a stent including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure in order to enhance a signal (col. 7, lines 7-24). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a dielectric part which also insulates, as taught by Da Silva et al., to Leopold et al. in order to better enhance a signal.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Da Silva et al.** (U.S. Patent No. **6,729,336**).

Claim 24: Leopold et al. disclose the claimed invention including a first ring and side beams and cross-bands, except for the elements including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure.

Da Silva et al. teach a stent including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure in order to enhance a signal (col. 7, lines 7-24). It would have been obvious to one of ordinary skill in the art



at the time of invention to provide a dielectric part which also insulates, as taught by Da Silva et al., to Leopold et al. in order to better enhance a signal.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-26 and 36-45 have been considered but are moot in view of the new ground(s) of rejection.
12. In regards to claims 46-47, the stent of Fischell et al. may considered to be disposed or positioned in a plane when in a non-expanded or non-deployed position as recited in the claims, and does not require the structure to be planar itself.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734